3-11-92

1378

DCN: 50-920001433

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

REGULATION OF A NEW CHEMICAL SUBSTANCE

PENDING DEVELOPMENT OF INFORMATION

In the matter of:	)	Premanufacture
	)	Notice Number:
	)	
	)	
	)	
	)	
SNPE, Inc.	)	P-91-391
	)	
	)	
	)	

Consent Order, Consent Order for Contract Manufacturer,

and Determinations Supporting Consent Orders

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I. INTRODUCTION

Under the authority of §5(e) of the Toxic Substances Control Act ("TSCA") (15 U.S.C. 2604(e)), the Environmental Protection Agency ("EPA" or "the Agency") issues the attached Orders, regarding premanufacture notice ("PMN") P-91-391 submitted by SNPE, Inc. ("the Company"), to take effect upon expiration of the PMN review period.

Under §15 of TSCA, it is unlawful for any person to fail or refuse to comply with any provision of §5 or any order issued under §5. Violators may be subject to various penalties and to both criminal and civil liability pursuant to §16, and specific enforcement and seizure pursuant to §17.

II. SUMMARY OF TERMS OF THE ORDER

The Consent Order imposes restrictions on the Company with respect to the manufacture, processing, use, and distribution in commerce of the PMN substance in the following areas: personal protective equipment for workers who may be dermally exposed; respiratory protection for workers who may be exposed to the PMN substance; written hazard communication program; labeling; Material Safety Data Sheets; employee information and training; manufacture by others; processing and use; distribution; and recordkeeping. A separate Consent Order for Contract Manufacturer is provided and is to be signed by each Contract Manufacturer.

III. CONTENTS OF PMN

No Confidential Business Information Claims.

Chemical Identity: 2-Propenoic acid, 2-(2-oxo-3-oxazolidinyl) ethyl ester.

Use: Reactive diluent in ultraviolent or electron beam curing of lithographic inks (50 percent); reactive diluent in industrial varnishes cured using ultraviolet or electron beam techniques (50 percent).

Maximum 12-Month Production Volume: 30,000 kilograms/year.

Toxicity Data Available on the PMN substance:

Acute Oral Toxicity:	LD_{50} = 909 mg/kg.
Dermal Irritation:	Slight dermal irritant.
Dermal Sensitization:	No dermal sensitization using the Buehler procedure.
Eye Irritation:	Significant and partially reversible eye lesions.
28-day Oral Gavage Study:	Statistically significant liver effects.

Industrial Hygiene Considerations:

When regulating similar acrylate compounds, the Agency typically requires that workers exposed to the PMN substance via inhalation in the form of dust, mist, or smoke wear National Institute for Occupational Safety and Health ("NIOSH")-approved category 23C respirators. However, for this PMN substance, EPA technical reviewers estimated that the substance may have an appreciable vapor pressure and that, as a result, workers also could be exposed to the PMN substance in the form of either a vapor or gas. Therefore, the Agency requested that the Company perform an organic vapor cartridge service life study for a NIOSH-approved category 23C respirator with organic vapor cartridge to ensure that this class of respirators would provide workers with adequate respiratory protection.

Based on the results of the submitted study, an organic vapor cartridge will provide adequate respiratory protection if the cartridges are changed at least every eight hours. In this light, provisions have been added to the "Protection in the Workplace" section of these Orders.

It should be noted that other contaminants and/or different workplace conditions may affect the cartridge service life. Therefore, EPA encourages the Company to consider these factors in determining the proper usage of the organic vapor cartridges.

IV. EPA'S ASSESSMENT

Health Effects Summary. Potential cancer based on analogy to other acrylates that have been shown to cause cancer in laboratory animals.

Exposure Summary:

	Manufacture	Process Varnish	Process Ink	Use Varnish	Use Ink
# Sites	Import.	1-2	1-2	5	5
# Persons/Site		3	3	3	3
# Days/year		40	80	100	100
Amt. Dermal Exp. (mg/day)		3900	3900	2000	585
Amt. Inhal. Exp. (mg/day)		20	10	1	0.5

V. EPA's CONCLUSIONS OF LAW

The following findings constitute the basis of the Consent Orders:

(a) EPA is unable to determine the potential for cancer from exposure to the PMN substance. EPA therefore concludes, pursuant to §5(e)(1)(A)(i) of TSCA, that the information available to the Agency is insufficient to permit a reasoned evaluation of the health effects of the PMN substance.

(b) In light of the absence of data to determine the potential risk of cancer posed by the uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance, and the Agency's conclusion that the issuance of the Orders will not result in any significant loss of benefits to society, EPA has concluded, pursuant to §5(e)(1)(A)(ii)(I) of TSCA, that uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance may present an unreasonable risk of injury to human health.

VI. INFORMATION REQUIRED TO EVALUATE HEALTH EFFECTS

Should the Company or the Contract Manufacturer desire to have these Orders modified or rescinded, the following information would assist in evaluating the risk posed by the PMN substance: A two-year cancer bioassay (test guidelines described in 40 CFR §798.3300). Toxicity data on representative members of the acrylate/methacrylate class of chemical substances being

developed by certain acrylate and methacrylate manufacturers may also be useful in evaluating the risk posed by the PMN substance.

Any test data submitted to the Agency should be developed according to the Toxic Substances Control Act ("TSCA") Good Laboratory Practice Standards at 40 CFR Part 792 (48 FR 53922, November 29, 1983) and through the use of methodologies generally accepted at the time the study is initiated. EPA encourages consultation with the Agency before protocol selection or information development. Failure to do so could result in data insufficient to permit a reasoned evaluation of the effects of the substance. Published test guidelines provide guidance for development of test protocols, but are not themselves acceptable protocols.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

CONSENT ORDER

I. TERMS OF MANUFACTURE, IMPORT, PROCESSING, DISTRIBUTION IN COMMERCE, USE, AND DISPOSAL PENDING SUBMISSION AND EVALUATION OF ADDITIONAL INFORMATION

SNPE, Inc. ("the Company") is prohibited from manufacturing, importing, processing, distributing in commerce, using, or disposing of the chemical substance 2-Propenoic acid, 2-(2-oxo-3-oxazolidinyl) ethyl ester ("the PMN substance") in the United States, for any non-exempt commercial purpose, pending the development of information necessary for a reasoned evaluation of the health effects of the substance, and the completion of EPA's review of that information, except under the following conditions:

PROTECTION IN THE WORKPLACE

(a) During manufacturing, processing, and use of the PMN substance at any site controlled by the Company, the Company must establish a program whereby:

(1) Each person who is reasonably likely to be dermally exposed in the work area to the PMN substance through direct handling of the substance or through contact with equipment on

which the substance may exist, or because the substance becomes airborne in a form listed in subparagraph (a)(5) is provided with, and is required to wear, personal protective equipment that provides a barrier to prevent dermal exposure to the substance in the specific work area where it is selected for use. Each such item of personal protective equipment must be selected and used in accordance with 29 CFR §1910.132 and 29 CFR §1910.133.

(2) In addition to any other personal protective equipment selected under paragraph (a)(1) of this section, the following items are required:

(i) Gloves.

(ii) Clothing which covers any other exposed areas of the arms, legs and torso. Clothing required under this subparagraph need not be tested or evaluated under the requirements of paragraph (a)(3) of this section.

(iii) Chemical goggles or equivalent eye protection.

(3) The Company is able to demonstrate that the personal protective clothing selected, including gloves, provides an impervious barrier to prevent dermal exposure during normal and expected duration and conditions of exposure within the particular defined work area by any one or a combination of the following:

(i) Testing the material used to make the chemical protective clothing to establish that the protective clothing will be impervious for the expected duration and conditions of exposure. The testing must subject the chemical protective

clothing to the expected conditions of exposure, including the likely combinations of chemical substances to which the clothing may be exposed in the work area.

(ii) Evaluating the specifications from the manufacturer or supplier of the chemical protective clothing or of the material used in construction of the clothing, to establish that the chemical protective clothing will be impervious to the chemical substance alone and in likely combination with other chemical substances in the work area.

(4) Each person who is reasonably likely to be exposed in the work area to the PMN substance by inhalation in the form listed in subparagraph (a)(5) is provided with, and is required to wear, at a minimum, a NIOSH-approved category 23-C air-purifying respirator equipped with combination cartridges approved for paints, lacquers and enamels, including disposable respirators. (Approval label may preclude use for some paints, lacquers, or enamels.) The respirator shall be used in accordance with 29 CFR §1910.134 and 30 CFR §11. Based on organic vapor cartridge service life data submitted by the Company, respirator cartridges shall be changed at least every eight hours.

(5) The following airborne forms of the PMN substance apply to subparagraphs (a)(1) and (4) of this section:

(i) Dust.

(ii) Mist.

(iii) Smoke.

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(iv) Fume.

(v) Vapor.

(vi) Gas.

(b) If the PMN substance is present in the work area only as a mixture, the Company is exempt from the provisions of this Protection in the Workplace section if the concentration of the PMN substance in the mixture does not exceed 1.0 percent or greater by weight or volume, or 0.1 percent or greater by weight or volume if paragraph (g) of the Hazard Communication Program section of the Order identifies cancer as a potential human health hazard of the PMN substance. This exemption does not apply if the Company has reason to believe that during intended use or processing in the work area, the PMN substance in the mixture may be reconcentrated above the 1.0 or 0.1 percent level, whichever is applicable.

HAZARD COMMUNICATION PROGRAM

(a) Written hazard communication program. The Company shall develop and implement a written hazard communication program for the substance in each workplace. The written program will, at a minimum, describe how the requirements of this section for labels, Material Safety Data Sheets ("MSDSs"), and other forms of warning material will be satisfied. The Company must make the written hazard communication program available, upon request, to all employees, contractor employees, and their designated

representatives ("employees") who may come in contact with the PMN substance. The Company may rely on an existing hazard communication program to comply with this paragraph provided that it satisfies the requirements of this section. The written program shall include the following:

(1) A list containing the identity of the PMN substance. The list must be maintained in each work area where the PMN substance is known to be present and must use the identity provided on the MSDS for the substance required under paragraph (c) of this section. The list may be compiled for the workplace or for individual work areas. If the Company is required either by another Order issued under section 5(e) of TSCA or by 40 CFR Part 721, Subpart E to maintain a list of substances, the list shall be combined with the list under this subparagraph.

(2) The methods the Company will use to inform employees of the hazards of non-routine tasks involving the PMN substance (e.g., cleaning of reactor vessels), and the hazards associated with the PMN substance contained in unlabeled pipes in their work area.

(3) The methods the Company will use to inform contractors of the presence of the PMN substance in the Company's workplace and the provisions of this Order if employees of the contractor work in the Company's workplace and are reasonably likely to be exposed to the PMN substance while in the Company's workplace.

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(b) Labeling.

(1) The Company shall ensure that each container of the PMN substance in the workplace is labeled in accordance with this paragraph (b)(1).

(i) The label shall, at a minimum, contain the following statement:

(A) The health effects of this chemical substance have not been determined.

(B) When using this substance, use skin protection.

(C) Use respiratory protection when there is a reasonable likelihood of exposure in the work area from dust, mist, smoke, fumes, vapor, or gas.

(D) The identity by which the PMN substance may be commonly recognized.

(ii) The Company may use signs, placards, process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual stationary process containers, as long as the alternative method identifies the containers to which it is applicable and conveys information specified by paragraph (b)(1)(i) of this section. Any written materials must be readily accessible to the employees in their work areas throughout each work shift.

(iii) The Company need not label portable containers into which the PMN substance is transferred from labeled

containers, and which are intended only for the immediate use of the employee who performs the transfer.

(iv) The Company shall not remove or deface an existing label on containers of the PMN substance obtained from persons outside the Company unless the container is immediately relabeled with the information specified in paragraph (b)(1)(i) of this section.

(2) The Company shall ensure that each container of the substance leaving its workplace for distribution in commerce is labeled in accordance with this paragraph.

(i) The label shall, at a minimum, contain the following information:

(A) The information prescribed in paragraph (b)(1)(i) of this section.

(B) The name and address of the manufacturer or a responsible party who can provide additional information on the substance for hazard evaluation and any appropriate emergency procedures.

(ii) The label shall not conflict with the requirements of the Hazardous Materials Transportation Act (18 U.S.C. 1801 et. seq.) and regulations issued under that Act by the Department of Transportation.

(3) The label or alternative form of warning shall be legible and prominently displayed.

(4) The label or alternative form of warning, shall be printed in English; however, the information may be repeated in other languages.

(5) If the label or alternative form of warning is to be applied to a mixture containing the PMN substance in combination with any other substance that is either subject to a TSCA section 5(e) Order applicable to the Company, or a TSCA section 5(a) Significant New Use Rule ("SNUR") at 40 CFR Part 721, subpart E, or defined as a "hazardous chemical" under the Occupational Safety and Health Administration ("OSHA") Hazard Communication Standard (29 CFR 1910.1200), the Company may prescribe on the label, MSDS, or alternative form of warning, the measures to control worker exposure or environmental release which the Company determines provide the greatest degree of protection. However, should these control measures differ from the applicable measures required under this Order, the Company must seek a determination of equivalency for such alternative control measures pursuant to 40 CFR 721.30 before prescribing them under this Order.

(c) Material Safety Data Sheets.

(1) The Company must obtain or develop an MSDS for the PMN substance.

(2) The MSDS shall contain, at a minimum, the following information:

(i) The identity used on the container label of the PMN substance under this section, and, if not claimed confidential, the chemical and common name of the PMN substance. If the chemical and common name are claimed confidential, a generic chemical name shall be used.

(ii) Physical and chemical characteristics of the PMN substance known to the Company, e.g., vapor pressure, flash point.

(iii) The physical hazards of the PMN substance known to the Company, including the potential for fire, explosion, and reactivity.

(iv) The potential human health hazards as specified in subsection (g) of this section.

(v) Signs and symptoms of exposure, and any medical conditions which are expected to be aggravated by exposure to the PMN substance known to the Company.

(vi) The primary routes of exposure to the PMN substance.

(vii) Precautionary measures to control worker exposure as identified in the Protection in the Workplace section of this Order, or alternative control measures which EPA has determined under 40 CFR 721.30 provide substantially the same degree of protection as the identified control measures.

(viii) Any generally applicable precautions for safe handling and use of the PMN substance which are known to the Company, including appropriate hygienic practices, protective

measures during repair and maintenance of contaminated equipment, and procedures for response to spills and leaks.

(ix) Any generally applicable control measures which are known to the Company, such as appropriate engineering controls, work practices, or personal protective equipment.

(x) Emergency first aid procedures known to the Company.

(xi) The date of preparation of the MSDS or of its last revision.

(xii) The name, address, and telephone number of the Company or another responsible party preparing or distributing the MSDS, who can provide additional information on the PMN substance and any appropriate emergency procedures.

(3) If no relevant information is found or known for any given category on the MSDS, the Company must mark the MSDS to indicate that no applicable information was found.

(4) Where multiple mixtures containing the PMN substance have similar compositions (i.e., the chemical ingredients are essentially the same, but the specific composition varies from mixture to mixture) and similar hazards, the Company may prepare one MSDS to apply to all of these multiple mixtures.

(5) If the Company becomes aware of any significant new information regarding the hazards of the PMN substance or ways to protect against the hazards, this new information must be added to the MSDS within 3 months of discovery of the new information. If the PMN substance is not being manufactured, imported,

processed, distributed in commerce, or used by the Company, the Company must add the new information to the MSDS before the substance is reintroduced into the workplace.

(6) The Company must ensure that persons receiving the PMN substance from the Company are provided a current MSDS with their initial shipment and with the first shipment after an MSDS is revised. The Company may either provide the MSDS with the shipped containers or send it to the person prior to or at the time of shipment.

(7) The Company must maintain a copy of the MSDS in its workplace, and must ensure that it is readily accessible during each work shift to employees when they are in their work area.

(8) The MSDS may be kept in any form, including as operating procedures, and may be designed to cover groups of substances in the work area where it may be more appropriate to address the potential hazards of a process rather than individual substances. However, in all cases, the required information must be provided for the substance and must be readily accessible during each work shift to employees when they are in their work areas.

(9) The MSDS must be printed in English; however, the information may be repeated in other languages.

(d) Employee information and training. The Company must ensure that employees are provided with information and training on the PMN substance. This information and training must be provided at

the time of each employee's initial assignment to a work area containing the PMN substance and whenever the PMN substance is introduced into the employee's work area for the first time.

(1) The information provided to employees under this paragraph shall include:

(i) The requirements of this section.

(ii) Any operations in the work area where the PMN substance is present.

(iii) The location and availability of the written hazard communication program required under paragraph (a) of this section, including the list of substances subject to a TSCA section 5(e) Consent Order signed by the Company or to a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E, and MSDSs required by paragraph (c) of this section.

(2) The training provided to employees shall include:

(i) Methods and observations that may be used to detect the presence or release of the PMN substance in or from an employee's work area (such as monitoring conducted by the Company, continuous monitoring devices, visual appearance, or odor of the substance when being released).

(ii) The potential human health hazards of the PMN substance as specified in paragraph (g) of this section.

(iii) The measures employees can take to protect themselves and the environment from the PMN substance, including specific procedures the Company has implemented to protect employees and the environment from exposure to the PMN substance,

including appropriate work practices, emergency procedures, personal protective equipment, engineering controls, and other measures to control worker exposure and/or environmental release required under this Order, or alternative control measures which EPA has determined under 40 CFR 721.30 provide the same degree of protection as the specified control measures.

(iv) The requirements of the hazard communication program developed by the Company under this section, including an explanation of the labeling system and the MSDS required by this section and guidance on obtaining and using appropriate hazard information.

(e) If the PMN substance is present in the work area only as a mixture, the Company is exempt from the provisions of this Hazard Communication Program section if the concentration of the PMN substance in the mixture does not exceed 1.0 percent or greater by weight or volume, or 0.1 percent or greater by weight or volume if paragraph (g) of this Hazard Communication Program section of this Order identifies cancer as a potential human health hazard of the PMN substance. This exemption does not apply if the Company has reason to believe that during intended use or processing in the work area, the PMN substance in the mixture may be reconcentrated above the 1.0 or 0.1 percent level, whichever is applicable.

(f) Existing hazard communication program. The Company need not take additional actions if existing programs and procedures satisfy the requirements of this section.

(g) Human health hazard precautionary statements. The following human health hazard and precautionary statements shall appear on the MSDS as specified in paragraph (c) of this section: Chemicals similar in structure to this substance have been found to cause cancer in laboratory animals. Avoid skin contact. When using this substance, use skin protection. Use respiratory protection when there is a reasonable likelihood of exposure in the work area from inhalation of dust, mist, smoke, fumes, vapor, or gas.

MANUFACTURING

(a) The Company shall not cause, encourage, or suggest the manufacture or import of the PMN substance by any other person, except as provided in Part II. of this Order.

(b) Paragraph (a) of this section shall expire 75 days after promulgation of a final SNUR governing the PMN substance under TSCA section 5(a)(2) unless EPA notifies the Company, in writing, on or before that day, of an action in a Federal Court seeking judicial review of the SNUR. If EPA so notifies the Company paragraph (a) of this section shall not expire until the Company

is notified that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(c) If EPA promulgates a final SNUR for the PMN substance, the Company shall notify each person whom it causes, encourages, or suggests to manufacture or import the PMN substance of the existence of the SNUR.

USE

(a) The Company shall not use the PMN substance in consumer products.

DISTRIBUTION

(a) The Company shall distribute the PMN substance only for non-consumer use.

(b) The Company shall distribute the PMN substance outside the Company, other than for disposal, only to a person who agrees to:

(1) Process the PMN substance only at a site in the person's control;

(2) Not use the PMN substance in consumer products;

(3) Comply with the same requirements and restrictions required of the Company in the Protection in the Workplace and Hazard Communication Program sections of this Order; and

(4) Not further distribute the PMN substance to any other person until after the PMN substance has been reacted (cured),

unless the PMN substance is present in concentrations of 0.1 percent or less by weight or volume and is not expected to be reconcentrated above the 0.1 percent level.

(c) Paragraphs (a) and (b) of this section shall expire 75 days after promulgation of a final SNUR for the PMN substance under section 5(a)(2) of TSCA, except as noted in paragraph (d) below, and unless EPA notifies the Company on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If EPA notifies the Company paragraphs (a) and (b) of this section shall not expire until the Company is notified that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(1) If EPA promulgates a final SNUR for the PMN substance, the Company shall notify each person to whom it distributes the PMN substance of the existence of the SNUR.

(d) If, at any time after commencing distribution in commerce of the PMN substance, the Company obtains knowledge that a recipient of the substance has failed to comply with any of the conditions specified in paragraph (b), the Company shall cease supplying the substance to that recipient, unless the recipient is in compliance with a SNUR for the PMN substance, or unless the Company is able to document each of the following:

(i) That the Company has, within 5 working days, notified the recipient in writing that the recipient has failed to comply with any of the conditions specified in paragraph (b).

(ii) That, within 15 working days of notifying the recipient of the noncompliance, the Company has received from the recipient, in writing, a statement of assurance that the recipient is aware of the terms of paragraph (b) of this section and will comply with those terms.

(iii) If, after receiving a statement of assurance from a recipient under subparagraph (d)(1)(ii) of this section, the Company obtains knowledge that the recipient has failed to comply with any of the conditions specified in paragraph (b) of this section, the Company shall cease supplying the PMN substance to that recipient, shall notify EPA of the failure to comply, and shall resume supplying the PMN substance to that recipient only upon written notification from the Agency.

RECORDKEEPING

(a) The Company shall maintain the following records until 5 years after the date they are created and shall make them available for inspection and copying by EPA in accordance with section 11 of TSCA:

(1) Records documenting the manufacture and importation volume of the PMN substance, including volume manufactured or imported by Contract Manufacturers, and the corresponding dates of manufacture and import;

(2) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture or import to whom the Company directly sells or transfers the PMN substance, the date of each sale or transfer, and the quantity of the substance sold or transferred on such date;

(3) Records documenting establishment and implementation of a program for the use of any applicable personal protective equipment required pursuant to the Protection in the Workplace section of this Order;

(4) Records documenting the determinations required by the Protection in the Workplace section of this Order that chemical protective clothing is impervious to the PMN substance;

(5) Records documenting establishment and implementation of the hazard communication program required by the Hazard Communication Program section of this Order;

(6) Copies of labels required under the Hazard Communication Program section of this Order;

(7) Copies of material safety data sheets required by the Hazard Communication Program section of this Order;

(8) Records documenting compliance with any applicable manufacturing, use, and distribution restrictions in the Manufacturing, Use, and Distribution sections of this Order.

(9) Any contracts required under Part II. of this Order.

TESTING NOTIFICATION

(a) The Company shall notify the EPA Laboratory Data Integrity Assurance Division, Office of Compliance Monitoring (EN-342), in writing of the following information within 10 days of scheduling any study intended to address the effects to health identified as the basis of this Order, or within 15 days after the effective date of this Order, whichever is later:

(1) The date when the study is scheduled to commence;

(2) The name and address of the laboratory which will conduct the study; and

(3) The name and telephone number of a person at the Company or the laboratory whom EPA may contact regarding the study.

II. MANUFACTURE OR IMPORT BY OTHERS

(a) The Company shall not cause, encourage, or suggest the manufacture or import of the PMN substance by any other person, except as provided below:

(1) The Company may cause the PMN substance to be manufactured or imported by a person outside the Company ("the Contract Manufacturer") only under the following conditions:

(i) The Contract Manufacturer must be under contract to the Company to manufacture or import the PMN substance solely for the Company. The contract must specify the identity of the PMN substance, the total quantities to be manufactured, and the basic technology to be used for manufacturing.

(ii) The Company shall obtain from each Contract Manufacturer a signed copy of the Consent Order for Contract Manufacturer, attached to this Order as Appendix A, and submit the copy to EPA. EPA must receive the signed copy of the Consent Order on or before the date that the Contract Manufacturer begins manufacture or import.

(iii) If, at any time, the Company has knowledge that the Contract Manufacturer has failed to comply with any of the conditions specified in the Consent Order for Contract Manufacturer, the Company shall immediately cease to cause the PMN substance to be manufactured or imported by the Contract Manufacturer, unless the Contract Manufacturer is in compliance with a SNUR for the PMN substance, or unless the Company is able to document each of the following:

(A) That the Company has, within 5 working days, notified the Contract Manufacturer in writing that the Contract Manufacturer has failed to comply with any of the conditions specified in the Consent Order for Contract Manufacturer.

(B) That, within 15 working days of notifying the Contract Manufacturer of the noncompliance, the Company received from the Contract Manufacturer, in writing, a statement of assurance that the Contract Manufacturer is aware of the terms of the Consent Order for Contract Manufacturer and will comply with those terms.

(C) If, after receiving a statement of assurance from the Contract Manufacturer under subparagraph (B) of this

section, the Company has knowledge that the Contract Manufacturer has failed to comply with any of the conditions specified in the Consent Order for Contract Manufacturer, the Company shall immediately cease to cause the PMN substance to be manufactured or imported by the Contract Manufacturer, shall notify EPA of the failure to comply, and shall cause manufacture or import of the PMN substance by the Contract Manufacturer only upon written notification from the Agency.

III. MODIFICATION AND REVOCATION OF CONSENT ORDER

The Company may petition EPA at any time, based upon new information on the health effects of or human exposure to the PMN substance, to modify or revoke substantive provisions of this Order. EPA will issue a modification or revocation if it determines that the activities proposed therein will not present an unreasonable risk of injury to health, and will not result in significant or substantial human exposure to the PMN substance in the absence of sufficient data to evaluate its effects on human health.

In addition, the Company may petition EPA at any time to make other modifications to the language of this Order. EPA will issue such a modification if it determines that the modification is useful, appropriate, and consistent with the structure and intent of this Order as issued.

IV. EFFECT OF CONSENT ORDER

By consenting to the entry of this Order, the Company waives its rights to file objections to this Order pursuant to §5(e)(1)(C) of TSCA, to receive service of this Order no later than 45 days before the end of the review period pursuant to §5(e)(1)(B) of TSCA, and to challenge the validity of this Order in any subsequent action. Consenting to the entry of this Order, and agreeing to be bound by its terms, does not constitute an admission by the Company as to the facts or conclusions underlying the Agency's determinations in this proceeding. This waiver does not affect any other rights that the Company may have under TSCA.

Date FEB - 7 1992

Linda J. Fisher
Assistant Administrator
for Pesticides, Toxic
Substances, and Prevention

Date March 3, 1992

Name: Thierry Malfroot

Title: Chief Executive Officer

Company: SNPE, Inc.